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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/22/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,957

Applicant(s)

MEIKLE ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 21-35, 37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4 and 6.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 21-35, 37 and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No.9. (Applicants indicated in the election that Applicants elect Group I, which includes claims 1-20 and 26. However, Group I actually includes claims 1-20 and 36, as indicated in the restriction requirement. Examiner assumes that Applicants intended to mean claim 36 instead of claim 26 as being part of Group I.)

Claim Objections

Claim 18 is objected to because of the following informalities: In claim 18, line 1, the word "order" should be --disorder. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague because it is not clear as to what level of saposin indicates the presence of the lysosomal storage disorder. The claim is also not clear as to what levels of saposin are involved in the monitoring of the lysosomal storage disorder. The claim is also not clear as to what level of saposin and/or which saposin is correlated to each of the lysosomal storage disorders. Page 4 of the specification indicates there are 30 lysosomal disorders and page 5 of the specification indicates there are 4 saposins. The detection of which saposin and at which level is indicative of the presence of which of the 30 possible lysosomal disorders?

Claims 11 and 12 are vague because it is not clear as to what level of saposin indicates progression of the disorder. The claim is also not clear as to which of the 30 possible lysosomal disorders is being referred to relative to the 4 possible saposins that are being measured.

Claim 7, line 1 recites the limitation "95% percentile". It appears that either "%" or "percentile" should be deleted since having both is redundant or confusing as to what Applicant means.

Claim 7 is also indefinite since it is not clear as to what a measured level that is greater than the 95% level in the control population indicates. For example, does it indicate the presence of the disorder?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 4, 7, 13-15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Brien et al. (1991) Saposin proteins: structure, function, and role in human lysosomal disorders, THE FASEB JOURNAL, vol. 5(3), 301-8.

As to claim 1, O'Brien discloses the method of monitoring a lysosomal storage disorder in a patient (page 306, right column, lines 21-22), comprising: measuring the level of at least one saposin in a tissue sample of the patient (page 306, right column, lines 17-19), wherein the level is an indicator of presence or extent of the disorder in the patient (page 306, right column, lines 21-22.)

As to claim 4, the measured level exceeds a mean level in a control population of individuals not having a lysosomal storage disorder, to indicate presence of the disorder in a patient (page 306, right column, lines 41-42.)

As to claim 7, the measured level is greater than the 95% level in the control population (page 306, right column, lines 41-42.)

As to claims 13 and 14, the saposin is selected from the group consisting of saposin A, B, C, D, and prosaposin (for example saposin A, page 306, right column, line 41.)

As to claim 15, the measuring step comprises detecting binding between a saposin polypeptide and an antibody (page 306, left column, lines 10-11.)

As to claim 17, the antibody is immobilized to a solid phase (page 306, right column, , line 18.)

As to claim 18, the lysosomal storage disorder is Niemann-Pick disease (page 306, right column, line 61.)

2. Claims 1-4, 7-10, 13-15, 17 and 18, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al., (2000) Saposins A, B, C, and D in Plasma of Patients with Lysosomal Storage Disorders.

As to claim 1, Change discloses the method of monitoring a lysosomal storage disorder in a patient (page 172, left column, second full paragraph), comprising: measuring the level of at least one saposin in a tissue sample of the patient (page 172, right column, third full paragraph), wherein the level is an indicator of presence or extent of the disorder in the patient (page 172, bottom to page 174, left column first paragraph.)

As to claim 2, the sample is a plasma sample (column 168, left column, second full paragraph.)

As to claim 3, the sample is whole blood sample (column 168, left column, second full paragraph.)

As to claim 4, the measured level exceeds a mean level in a control population of individuals not having a lysosomal storage disorder, to indicate presence of the disorder in a patient (page 172, right column, third full paragraph.)

As to claim 7, the measured level is greater than the 95% level in the control population (page 172, right column, third full paragraph.))

As to claim 8, the patient is not known to have a lysosomal storage disorder before the measuring step (page 172, left column, second full paragraph.)

As to claims 9 and 10, the patient is an infant less than one year old (page 167, right column, third full paragraph.)

As to claims 13 and 14, the saposin is selected from the group consisting of saposin A, B, C, D, and prosaposin (page 172, right column, third full paragraph.)

As to claim 15, the measuring step comprises detecting binding between a saposin polypeptide and an antibody (page 172, left column, last paragraph.)

As to claim 17, the antibody is immobilized to a solid phase (page 168, right column, second full paragraph.)

As to claim 18, the lysosomal storage disorder is Niemann-Pick disease (page 168, left column, first paragraph.)

As to claim 19, the method includes informing the patient or a parent or guardian thereof of the presence of the lysosomal storage disorder (page 167, right column, first and second full paragraphs.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 5, 6, 11, 12, 20 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al., (2000) Saposins A, B, C, and D in Plasma of Patients with Lysosomal Storage Disorders, Clinical Chemistry, vol. 46(2), 167-173.

Chang discloses the invention substantially as claimed. More specifically, Chang discloses that lysosomal storage disorders affects children, and that several lysosomal storage disorders have been responsive to treatments such as bone marrow transplant and enzyme replacement therapy (page 167, right column, first full paragraph.)

Thus, as to claims 5 and 11, it would have been obvious to measure the level of the saposin in a second tissue sample from the patient, the first and second samples being obtained at different times; and comparing the levels in the samples to indicate progression of the disease since Chang teaches that some lysosomal storage disorders can be responsive to treatment, thus teaching that after treatment, the disorder can be detected by the disclosed method to determine whether the disorder is responsive to the treatment.

Similarly, as to claims 6, 12 and 36, it would have been obvious to measure the level of saposin in a patient known to have a lysosomal storage disorder, wherein the patient is being treated for the disorder, and the level of the saposin indicates response

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to treatment since Chang teaches that some lysosomal storage disorders can be responsive to treatment, thus teaching that patients can undergo one of these treatments for lysosomal disorder, and after treatment, the disorder can be detected by the disclosed method to determine whether the disorder is responsive to the treatment. As to claim 12, because Chang discloses that saposins are reported to be increased in samples from lysosomal storage disorder patients, the level of the saposin indicates response to treatment. Likewise, as to claim 36, because Chang discloses that saposins are reported to be increased in samples from lysosomal storage disorder patients, a reduction in the level after treatment indicates a positive treatment outcome.

Similarly, as to claim 20, it would have been obvious to determine a treatment program based on the measurement since Chang teaches that some lysosomal storage disorders can be responsive to treatment, thus teaching that patients can undergo one of these treatments for lysosomal disorder.

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien, et al. (1991) Saposin proteins: structure, function, and role in human lysosomal disorders, THE FASEB JOURNAL, vol. 5(3), 301-8, in view of Stastny, J., et al. (1992) Production and Characterization of a Monoclonal Antibody to Human Saposin C, HYBRIDOMA, vol. 11, 351-359.

O'Brien discloses the invention substantially as claimed (see above), except for the antibody being a monoclonal antibody.

Stastny discloses a monoclonal antibody (68-12) that reacts with saposin C. It would have been obvious to use this monoclonal antibody in the O'Brien method to detect the level of saposin C because the high specificity of monoclonal antibodies for their corresponding antigen (in this case saposin C) would provide for a more sensitive assay for the detection of saposin C.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Meikle, P.J. et al. (1997) Diagnosis of lysosomal storage disorders: evaluation of lysosome associated membrane protein LAMP-1 as a diagnostic marker, CLINICAL CHEMISTRY, vol. 43(8), 1325-35. Meikle teaches the early diagnosis of lysosomal storage disorders using protein LAMP-1 as a diagnostic marker (page 1325, left column, first paragraph), and that detection of lysosomal storage disorders can be detected from samples in whole blood, placenta and newborns.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. 


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